

Application No. 10/615,844
Reply to Office Action of March 28, 2008

Docket No.: 3560-0131P

REMARKS

Applicants thank the Examiner for the thorough consideration given the present application. Claims 1-22 are currently being prosecuted. The Examiner is respectfully requested to reconsider the rejections of record in view of the claim amendment and the remarks set forth below.

Entry of Claim Amendment

Claim 1 is amended to remove language that does not have proper antecedent basis, and substitute language that has proper antecedent basis, in the claim without changing the scope of the claim. Specifically, claim 1 recites "one of said outlet openings" whereas the only previous basis for that language is "at least one outlet opening." Thus, the language "said openings" does not have proper antecedent basis in claim 1. Because of this, claim 1 is amended to change "one of said outlet openings" to read -- said at least one outlet opening --. This amendment does not require further consideration or search of the prior art, but merely makes claim 1 clear and definite by correcting achromatically error and by resolving an antecedent basis issue.

Rejection under 35 U.S.C. § 103

Claims 1-4, 6, 7, 11, and 12 stand rejected under 35 U.S.C. § 103 as being obvious over Edwards et al. (U.S. Patent No. 5,536,240) in view of Singh (U.S. Patent No. 6,599,237). This rejection is respectfully traversed.

Because the rejection is based on 35 U.S.C. §103, what is in issue in such a rejection is "the invention as a whole, "not just a few features of the claimed invention. Under 35 U.S.C.

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§103, " [a] patent may not be obtained . . . if the differences between the subject matter sought to be patented and the prior art are such that the subject matter *as a whole* would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains." The determination under §103 is whether the claimed invention *as a whole* would have been obvious to a person of ordinary skill in the art at the time the invention was made. *See In re O'Farrell*, 853 F.2d 894, 902, 7 USPQ2d 1673, 1680 (Fed. Cir. 1988). In determining obviousness, the invention must be considered as a whole and the claims must be considered in their entirety. *See Medtronic, Inc. v. Cardiac Pacemakers, Inc.*, 721 F.2d 1563, 1567, 220 USPQ 97, 101 (Fed. Cir. 1983).

In rejecting claims under 35 U.S.C. §103, it is incumbent on the Examiner to establish a factual basis to support the legal conclusion of obviousness. *See In re Fine*, 837 F.2d 1071, 1073, 5 USPQ2d 1596, 1598 (Fed. Cir. 1988). In so doing, the Examiner is expected to make the factual determinations set forth in *Graham v John Deere Co.*, 383 U.S. 1, 17, 148 USPQ 459, 467 (1966), and to provide a reason why one of ordinary skill in the pertinent art would have been led to modify the prior art or to combine prior art references to arrive at the claimed invention. Such reason must stem from some teaching, suggestion or implication in the prior art as a whole or knowledge generally available to one having ordinary skill in the art. *See Uniroyal Inc. v. F-Wiley Corp.*, 837 F.2d 1044, 1051, 5 USPQ2d 1434, 1438 (Fed. Cir. 1988), *cert. denied*, 488 U.S. 825 (1988); *Ashland Oil, Inc. v Delta Resins & Refactories, Inc.*, 776 F.2d 281, 293, 227 USPQ 657, 664 (Fed. Cir. 1985), *cert. denied*, 475 U.S. 1017 (1986); *ACS Hospital Systems, Inc. v Montefiore Hospital*, 732 F.2d 1572, 1577, 221 USPQ 929, 933 (Fed. Cir. 1984). These showings by the Examiner are an essential part of complying with the burden of

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presenting a *prima facie* case of obviousness. *See In re Oetiker*, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992). The mere fact that the prior art may be modified in the manner suggested by the Examiner does not make the modification obvious unless the prior art suggested the desirability of the modification. *See In re Fritch*, 972 F.2d 1260, 1266, 23 USPQ2d 1780, 1783 84 (Fed. Cir. 1992). To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be suggested or taught by the prior art. *See In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1970). All words in a claim must be considered in judging the patentability of that claim against the prior art. *See In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970).

A suggestion, teaching, or motivation to combine the prior art references is an "essential evidentiary component of an obviousness holding." *See C.R. Bard, Inc. v. M3 Sys. Inc.*, 157 F.3d 1340, 1352, 48 USPQ2d 1225, 1232 (Fed. Cir. 1998). This showing must be clear and particular, and broad conclusory statements about the teaching of multiple references, standing alone, are not "evidence." *See In re Dembiczaik*, 175 F.3d 994 at 1000, 50 USPQ2d 1614 at 1617 (Fed. Cir. 1999).

Moreover, it is well settled that the Office must provide objective evidence of the basis used in a prior art rejection. A factual inquiry whether to modify a reference must be based on objective evidence of record, not merely conclusory statements of the Examiner. *See In re Lee*, 277 F.3d 1338, 1343, 61 USPQ2d 1430, 1433 (Fed. Cir. 2002).

Furthermore, during patent examination, the PTO bears the initial burden of presenting a *prima facie* case of unpatentability. *See In re Oetiker*, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992); *In re Piasecki*, 745 F.2d 1468, 1472, 223 USPQ 785788 (Fed. Cir. 1984).

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If the PTO fails to meet this burden, then the Applicant is entitled to the patent. Only when a *prima facie* case is made, the burden shifts to the applicant to come forward to rebut such a case.

Claim 1 recites a combination of features including a urethral probe adapted to be inserted within a urethra; a catheter probe having an elongated body with a circumferential surface, a distal end and a proximal end, which catheter probe is adapted to be inserted in said urethral probe with its proximal end within the urethra towards the prostate; said elongated body of said catheter probe having a longitudinal bore extending from said distal end towards at least one outlet opening present in said circumferential surface near said proximal end; a catheter tube having a distal end and a proximal sharp end, which catheter tube is to be inserted with its proximal sharp end through said longitudinal bore of said elongated body, through one of said outlet openings and through said urethral wall towards at least one desired location within the prostate to be treated; said urethral probe being made of a material to be perforated by said proximal sharp end of said catheter tube at arbitrary positions relative to the prostate; and means for delivering a certain pre-planned amount of radiation energy via said catheter tube near or at said at least one desired location within said prostate for effecting said radiation treatment, said catheter probe being movably accommodated within said urethral probe.

Applicants respectfully submit that neither of the applied references discloses this combination of features. More specifically, neither applied reference discloses a urethral probe being made of a material to be perforated by said proximal sharp end of said catheter tube at arbitrary positions relative to the prostate.

Edwards, the primary reference used in the rejection, clearly has a single, fixed guide tube 134, to provide a single position along the housing that is inserted into the body opening,

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and contains no concept whatsoever of a guide tube that is made of a material to be perforated at arbitrary positions by a catheter tube with a sharp end.

Singh, the secondary reference used in the rejection, clearly has no concept whatsoever of a guide tube (sheath) that can be perforated by a surgical instrument in any manner whatsoever. Singh's surgical instrument 68 is clearly disclosed as merely moving through the sheath 10 from one open end of the sheath 10 through the opposite end of sheath 10. The only reason that Singh provides a sheath 10 that has a weakness separation line 71 is so that sheath 10 can open up to accommodate insertion of a surgical instrument 68 having a larger diameter than can be accommodated by lumen 18 of the sheath 10. There is no disclosure whatsoever of penetration of the sheath 10 by a surgical instrument at arbitrary positions relative to a prostate.

Because neither of these two references contains such a disclosure, there is no logical basis to conclude that any modification of these two references will result in, suggest, or otherwise render obvious this positively claimed feature that is missing from both references.

Another way of stating this is with reference to the lyrics of a song from the musical hit, "The Sound of Music." One of the songs in that musical contains the language "nothing comes from nothing, nothing ever could . . ."

Because the applied references contain nothing of a urethral probe being made of a material to be perforated by said proximal sharp end of said catheter tube at arbitrary positions relative to the prostate, there is no proper basis in either reference to meet, suggest, or otherwise render obvious the claimed invention.

Turning to the rejection's rationale for modifying Edward's urethral probe to have a material that is capable of being perforated, the reason for doing this is to permit more accurate

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positioning of a therapy delivering catheter. Unfortunately, no explanation of why the modified version of Edward would permit more accurate positioning of its catheter 54 is provided. In other words, this rationale is just speculation unsupported by fact. Actually, Applicants respectfully submit that the proposed modification of Edwards would result in a device that would be no more accurate regarding positioning of the catheter 54. Edwards' catheter 54 is guided to a specific location using guide channel 61. The proposed modification of Edwards would presumably not do away with the guide channel 61 (this issue not being addressed in the rejection). Thus, there would be no catheter positioning accuracy advantage in the proposed modification of Edwards.

In fact, because Edwards' catheter 56 has to be contained inside of guide 61, there is no incentive to make sleeve 50 out of a perforatable material because the external diameter of Edwards' catheter 56 can never, ever, be larger than the internal diameter of sleeve 50. Thus, one of ordinary skill in the art would have absolutely no incentive to modify Edwards' sleeve 50 to make it out of a perforatable material for the reason taught by Singh.

Additionally, Applicants respectfully submit that these two references differ so much from one another that they teach away from being combined as suggested in this rejection. In this regard, Applicants note that, to establish a *prima facie* case of obviousness, one must show "some objective teaching in the prior art or that knowledge generally available to one of ordinary skill in the art would lead that individual to combine the relevant teachings of the references." *See In re Fine*, 837 F.2d 1071 at 1074, 5 USPQ2d 1596 at 1598. There is no suggestion to combine, however, if a reference teaches away from its combination with another source. *See id.* at 1075, 5 USPQ2d at 1599. "A reference may be said to teach away when a

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person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the applicant . . . [or] if it suggests that the line of development flowing from the reference's disclosure is unlikely to be productive of the result sought by the applicant." *See In re Gurley*, 27 F.3d 551, 553, 31 USPQ2d 1130, 1131 (Fed. Cir. 1994). If when combined, the references "would produce a seemingly inoperative device," then they teach away from their combination. *See In re Sponnoble*, 405 F.2d 578, 587, 160 USPQ 237, 244 (CCPA 1969). *See also In re Gordon*, 733 F.2d 900, 902, 221 USPQ 1125, 1127 (Fed. Cir. 1984) (finding no suggestion to modify a prior art device where the modification would render the device inoperable for its intended purpose).

One significant difference between Edwards and Singh is the fact that Edwards is not intended to be used in a urethra because its configuration has inflatable balloons in order to secure in within a patient, whereas Singh is designed to be used in a urethra.

Another significant difference between the devices is that Edwards is not meant to be destroyed in use, whereas Singh's sheath is meant to be ruptured along its length and is not reusable, and this fact alone would deter one of ordinary skill in the art from modifying Edwards to result in a single use device.

Moreover, the rejection is based on the premise that one of ordinary skill in the art would use the catheter of the modified version of Edwards to rupture the perforated the line 71 of the modified version of Edwards, something that is not taught in either applied reference, and something that results in frictional contact between the perforated portion (and its surroundings) of the sheath and the inner wall of a patient's urethra, causing significant discomfort to the

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patient. Thus, the proposed modification of Edwards and its resulting mode of operation clearly teaches away from making the proposed modification of Edwards in view of Singh.

This is to be distinguished from the claimed invention, which does not have these discomforting features associated with it.

Accordingly, Applicants respectfully submit that the only basis for this rejection is either improper speculation, devoid of a factual prior art basis, or impermissible hindsight reconstruction of the claimed invention based solely on Applicants' disclosure.

Further, with respect to claim 4, this claim positively recites a combination of features including the features of claim 1 and that the inner dimensions of the longitudinal urethral probe are slightly larger than the outer dimensions of the catheter probe. This is not the case with either Edwards or Singh. In Edwards, the inner diameter of urethral probe 50 is vastly larger than the outer diameter of catheter probe 56, and in Singh, the inner diameter of perforatable urethral probe 12 is actually smaller than the outer diameter of catheter probe 68.

Thus, even if these two references were properly combined, which they are not, for reasons explained above, the modified version of Edwards would still not meet, suggest, or otherwise render obvious, the claimed invention.

Accordingly, the Office Action does not make out a *prima facie* case of obviousness of the invention recited in claims 1-4, 6, 7, 11 and 12, and should be withdrawn.

Claim 5 stands rejected under 35 U.S.C. § 103 as being obvious over Edwards and Singh, as applied in the rejection of claim 1, and further in view of Shiber (U.S. Patent No. 5,135,531).

Claims 8-10, 18 and 19 stand rejected under 35 U.S.C. § 103 as being obvious over Edwards and Singh, as applied in the rejection of claim 1, and further in view of Kindlein et al. (U.S. Patent

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No. 6,454,696). Claim 13 stand rejected under 35 U.S.C. § 103 as being obvious over Edwards and Jagpal (U.S. Patent No. 5,257,979) and further in view of Webster (U.S. Patent No. 5,569,220). Claims 14-17 stand rejected under 35 U.S.C. § 103 as being obvious over Edwards, Jagpal and Webster and further in view of Tiller et al. ("Tiller" - U.S. Published Application 2003/0091641). Claims 20 and 21 stand rejected under 35 U.S.C. § 103 as being obvious over Edwards and Singh, as applied in the rejection of claim 1, and further in view of Bradshaw et al. ("Bradshaw" - U.S. Patent No. 5,139,473). Claim 22 stand rejected under 35 U.S.C. § 103 as being obvious over Edwards over Singh, as applied in the rejection of claim 1, and further in view of Hung et al. ("Hung" - U.S. Patent No. 6,391,026). These rejections are respectfully traversed.

All of these claims depend from claim 1, which is not rendered obvious for reasons presented above. Moreover, none of the secondary references are applied to remedy the deficiencies of Edwards or Singh. Accordingly, the Office Action fails to make out a *prima facie* case of obviousness of the invention recited in claims 5, 8-10 and 13-22.

Applicants submit that even if the secondary references show the various features of the dependent claims, these claims remain allowable based on their dependency from allowable claim 1.

Furthermore, the rejections of claims 13-17 do not address the positively recited feature of a urethral probe being made of a material to be perforated by said proximal sharp end of said catheter tube at arbitrary positions relative to the prostate, omitting discussion of that feature, and not applying a reference to support a rejection of that feature. For this additional reason, the rejection of claims 13-17 is fundamentally improper and is without merit.

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Accordingly, the Office Action does not make out a *prima facie* case of obviousness of the invention recited in claims 5, 8-10 and 13-22, and should be withdrawn.

Conclusion

In view of the above remarks, it is believed that claims clearly distinguish over the patents relied on by the Examiner, either allow or in combination. In view of this, reconsideration of the rejection and allowance of all the claims are respectfully requested.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Robert J. Webster, Reg. No. 46,472, at the telephone number of the undersigned below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37.C.F.R. §§1.16 or 1.14; particularly, extension of time fees.

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Respectfully submitted,

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